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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,524	04/01/2002	Ryoichi Sakaue	221513USOPCT	9274

22850 7590 02/24/2004

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EXAMINER

LEARY, LOUISE N

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

S.A.M.

**Office Action Summary****Application No.**

10/088,524

**Applicant(s)**

SAKAUE ET AL.

**Examiner**

Louise N. Leary

**Art Unit**

1654

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 December 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 33 and 34 is/are allowed.
- 6) ☒ Claim(s) 13-17, 19, 20, 22, 29, 31, 32, 40 and 3538 is/are rejected.
- 7) ☒ Claim(s) 18, 21, 23-28, 30, 36 and 37 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

1. Claims 3-40 are pending in this application.

Claims 1-12 have been canceled without prejudice per applicant's request.

2. The rejection of claims 1, 6, 8 and 9 under 35 USC 102(b) as anticipated by or, in the alternative, under 35 USC 103(a) as obvious over Yonehara et al (JP-324732, Nov. 26, 1997) is moot because original claims 1, 6, 8, and 9 have been canceled.

3. NEW GROUNDS OF REJECTION:

Claims 13-20, 22, 29, 31-32, 35, 38-40 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Yonehara et al (US 5,985,591).

4. Applicant's arguments filed December 1, 2003 have been fully considered but they are not persuasive.

Applicants have argued Yonehara, English Abstract, discloses treating a saccharified protein with a protease and a then treating with a fructosyl amino acid oxidase (FAOD). However, the method of the present invention requires the use of an oxidase which reacts with a glycated peptide. Yonehara neither discloses with sufficient specificity any such oxidase reactive with a glycated peptide, nor does it suggest that one select such an oxidase." See page 8 of applicant's amendment filed 12-1-2003. However, the examiner respectfully disagree with applicant's arguments because Yonehara et al (JP 9-324732, November 26, 2997) (English Abstract) acknowledges that US Patent number 5,985,591 is the English equivalent. US Patent number 5,985,591 was made of record in the Office Action dated August 28, 2003.

Yonehara et al disclose a method for assaying the presence of a glycosylated peptide in a sample comprising the steps of treating the sample with at least one oxidase which produces peroxide. Yonehara et al disclose the use of an oxidase derived from *Corynebacterium*. In addition, Yonehara et al disclose the use of a protease in the assay method. Yonehara et al disclose measuring the amount of glycosylated protein in samples to evaluate diabetic conditions. See this entire document.

Thus, Yonehara et al disclose or suggest the invention claimed except for using the word "kit".

However, Yonehara et al disclose each component in the kit claimed for performing the same function set forth in the instant invention. Therefore, Yonehara et al disclose all the limitations of the instant claims except for using the word "kit" but describes each component and the properties or functions claimed in the present invention which anticipates or renders obvious the invention as claimed.

The burden of proof is on applicants to show patentably distinct differences between the Yonehara et al methods and reactants and the present invention as claimed.

5. Claims 18, 21, 23-28, 30, and 36-37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 1654

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is (703) 308-3533. The examiner can normally be reached on Monday to Friday from 10 to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

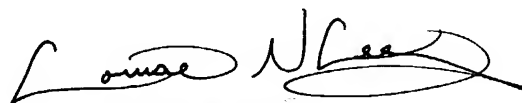
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

Application/Control Number: 10/088,524

Page 5

Art Unit: 1654

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LOUISE N. LEARY  
PRIMARY EXAMINER

February 20, 2004